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Experience with the GORE EXCLUDER iliac branch endoprosthesis for common iliac artery aneurysms

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Objective: **In this study, we analyzed the procedural success and early outcome of endovascular treatment of a multicenter cohort of patients with common iliac artery (CIA) aneurysms treated with the new GORE EXCLUDER (W. L. Gore & Associates, Flagstaff, Ariz) iliac branch endoprosthesis (IBE).**

Methods: **A retrospective cohort analysis was performed in 13 sites in The Netherlands. Anatomic, demographic, procedural, and follow-up data were assessed from hospital records.**

Results: **From November 2013 to December 2014, 51 CIA aneurysms were treated with an IBE in 46 patients. The median diameter of the treated aneurysm was 40.5 (range, 25.0-90.0) mm. The mean procedural time was 198 ± 56 minutes. All but one implantation were successful; two type Ib endoleaks were noticed, resulting in a procedural success rate of 93.5%. The two type Ib endoleaks spontaneously disappeared at 30 days. There was no 30-day mortality. Ipsilateral buttock claudication was present in only two cases at 30 days and disappeared during follow-up. The incidence of reported erectile dysfunction was low and severe ischemic complications were absent. After a mean follow-up of 6 months, data on 17 treated aneurysms were available. Two showed a stable diameter, whereas 15 showed a mean decrease of 3.9 ± 2.2 mm ($P < .001$). Reinterventions were performed in two patients (7.1%). The 6-month primary patency of the internal component of the IBE device was 94%.**

Conclusions: **The use of the GORE EXCLUDER IBE device for CIA aneurysms is related to high procedural success, high patency rates, and low reintervention rates at short-term follow-up. Prospective data with longer follow-up are awaited to establish the role of the device in the treatment algorithm of CIA aneurysms. (J Vasc Surg 2016;63:1451-7.)**

Endovascular aortic aneurysm repair (EVAR) of abdominal aneurysms has gradually replaced open surgical repair and is now an established treatment modality. EVAR results in reduced operative blood loss, reduced length of stay in the intensive care unit, and is related to lower 30-day mortality rates.[1] The applicability of standard EVAR has been challenged by involvement of the visceral arteries and/or aneurysm extension into the iliac arteries. An isolated aneurysm of the common iliac artery (CIA) is uncommon, but in relation to an abdominal aneurysm, it is found in 20% to 40% of cases.[2]

Various strategies have been applied to enable EVAR in CIA aneurysms. Intentional occlusion of the hypogastric artery by coiling and covering might be safe, but it can cause gluteal claudication (16%-55%) and erectile dysfunction (10%-46%), or even more devastating complications such as colonic or spinal cord ischemia.[3-5] Better results might be achieved by only covering the internal iliac artery (IIA), but this technique can result in a persistent type II endoleak with uncertain long-term results.[6] To reduce the incidence of ischemic complications, other techniques have been used, including the use of bell-bottom limbs and the off-label use of endografts.[7,8] The Zenith Iliac branched device (Cook, Brisbane, Queensland, Australia) was the first dedicated device to preserve hypogastric flow after EVAR of CIA aneurysms. The device consists of a single component and is used with various types of grafts to extend into the IIA.[9] Results are encouraging, but endoleak rates of 3% to 30% and occlusion rates up to 12% have been described.[10-12] These data might partly reflect a general early learning curve for iliac branch devices (IBDs). More recently, the GORE EXCLUDER iliac branch endoprosthesis (IBE; W. L. Gore & Associates, Flagstaff, Ariz) was developed. The system is based on the Excluder platform and is combined with a dedicated internal iliac component. Conformité Européenne mark for

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the device was gained in November 2013. In this report, we describe a multicenter national retrospective cohort study with the use of the IBE device in CIA aneurysms. The primary focus of this study was to evaluate procedural success and additionally to determine short-term iliac branch patency. Secondary outcomes were patency, clinical symptoms of ischemia, and CIA aneurysm diameters.

METHODS

All Dutch centers with experience in IBE device implantation were invited to collaborate in this study (Supplementary Table). Retrospective data were captured in a database. Anatomical details were measured from the computed tomography (CT) scans by the vascular surgeon or interventional radiologist. Each operator was responsible for sizing and planning of their own procedures. Demographic, procedural, and postprocedural data were assessed from hospital records and coded in the database. Results are reported according to the reporting standards for EVAR.[13] Retrospective "patient files" research is not in scope of the Dutch Wet Mensgebonden Onderzoek: law human bound research and institutional review board approval was therefore not required. As a consequence, patient informed consent was not obtained. Patient data were analyzed anonymously.

Treatment. The IBE is designed to provide endovascular treatment of CIA or aortoiliac aneurysms as a dedicated device to be used in conjunction with the GORE EXCLUDER endoprosthesis (Fig 1). Anatomical limitations are described in the instructions for use (IFU) and include a CIA diameter of at least 17 mm proximal of the implantation zone of the IBE. The nonaneurysmal length of the external iliac artery (EIA) should be at least 10 mm with a diameter of 6.5 to 13.5 mm, or with a diameter range of 6.5 to 25 mm in case an extension is used. The diameter of the IIA should be 6.5 to 13.5 mm with a distal sealing zone length of at least 10 mm. There is no limitation regarding the length of the CIA. A minimal distance of 165 mm between the lowest renal artery and the iliac bifurcation is required. The system is introduced through a 16-F sheath and is designed to achieve high conformability and sealing in tortuous iliac arteries. The IBE device is introduced over a stiff guide wire. The internal iliac branch is preloaded with a small removable guide wire tube, which is used to snare a crossover guide wire to the contralateral femoral site. Subsequently, the IBE system is introduced over the stiff and the crossover wire, with special attention for adequate position of the two wires. If necessary, the two-stage IBE deployment system offers repositionability of either distal movement or 90° in either direction at the level of the IIA. After the first step deployment and proper positioning of the IBE body, a contralateral flexible 12-F sheath is introduced over the crossover wire and positioned into the internal iliac limb of the IBE. A second wire is used to catheterize the IIA, and after replacement with a stiff wire, the dedicated iliac component is correctly positioned and deployed, followed by the second step of deployment of the IBE leg into the EIA. In case of aortoiliac aneurysms, a standard Excluder device is placed via the contralateral site using a GORE EXCLUDER bridging stent with the IBE. A case example is presented in Fig 2. Another case example is presented in Fig 3 to illustrate the deployed IBE device with the crossover sheath in the body of the device. Follow-up was conducted according to the local protocols of the collaborating sites.

Fig 1. Image of the GORE EXCLUDER iliac branch endoprosthesis (IBE). Image courtesy of W. L. Gore & Associates.

Definitions. The primary outcome of the study was procedural success of implanting, defined as the successful implantation of the IBE device with a patent side branch without a type I or III endoleak at completion angiography. Secondary outcomes were patency at 30 days and final follow-up visit, change in CIA aneurysm diameter, and clinical symptoms of ischemia. Patency was defined as the absence of thrombosis assessed using either CT or duplex ultrasound. A stenosis was defined as a peak systolic velocity ratio >2.5, measured using duplex ultrasound scanning or >50% luminal narrowing on CT scan. The change in CIA diameter (preprocedure vs follow-up) was defined as the absolute difference between time points, measured on CT scan or duplex ultrasound, whichever is available. Symptoms of ischemia included patient-reported

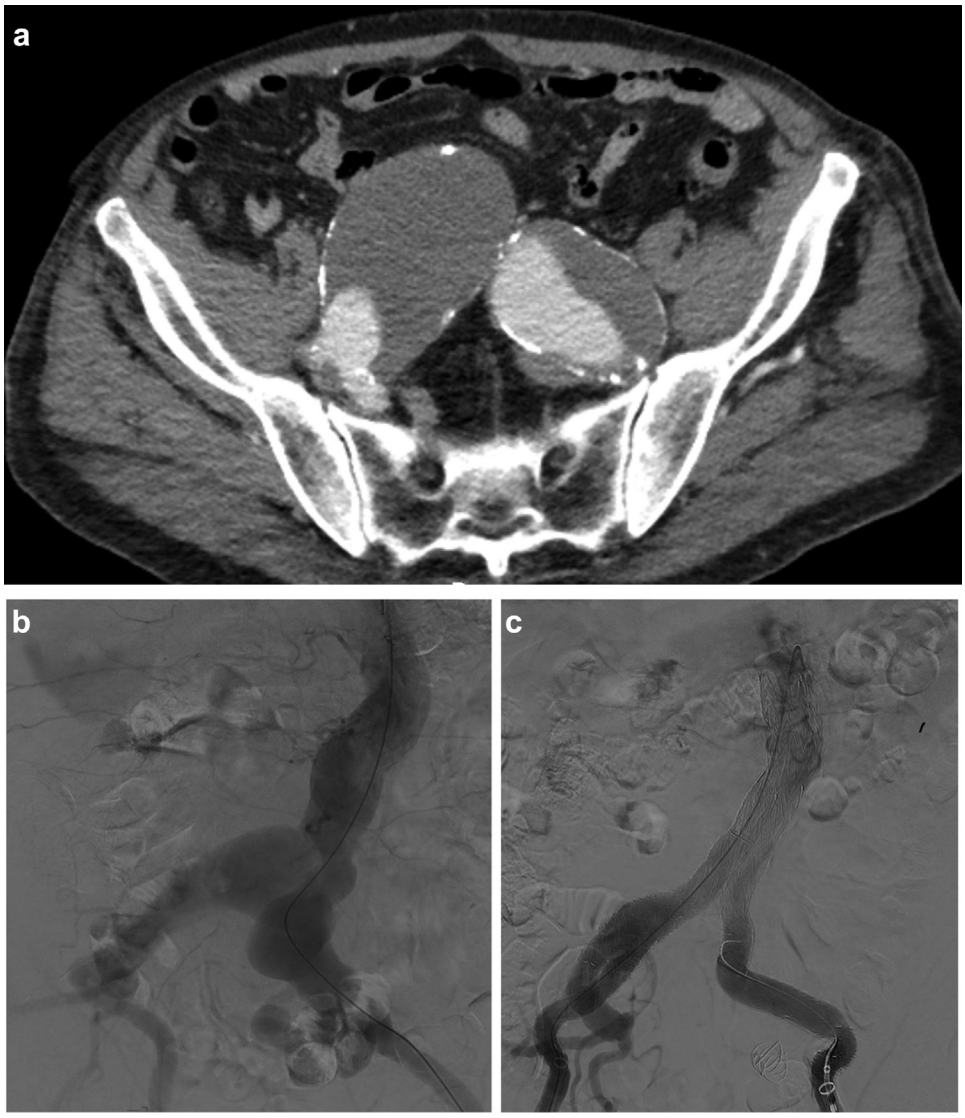

Fig 2. a, Transversal slide of the preoperative contrast-enhanced computed tomography (CT) image of a 77-year-old male patient showing bilateral common iliac artery (CIA) aneurysms of 63 and 48 mm on the right and left side, respectively. **b,** Procedural angiography of the patient. **c,** Completion angiography after placement of a GORE EXCLUDER iliac branch endoprosthesis (IBE) device at the right side and coil-and-covering on the left side, showing a complete exclusion of the CIA aneurysms and patent flow through the right-sided internal iliac artery.

buttock claudication, erectile dysfunction, and colonic of spinal ischemia. Other outcome measures were procedural time, hospitalization time, major and minor adverse events, and aneurysm-related and overall mortality.

Statistical analysis. Continuous variables are presented as mean and standard deviation or median and range when appropriate, and categorical variables as number and percentage. The Shapiro-Wilk test was used to examine if continuous variables followed the normal distribution. If not normally distributed, variables were log-transformed before testing. Repeated measures analysis of variance were used to compare diameters between different time points. Two-sided P values $<.05$ were considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 21.0 (IBM Corp, Armonk, NY).

RESULTS

From November 2013 to December 2014, a total of 51 CIA aneurysms were treated with an IBE in the participating centers in 46 patients with a mean age of 70.2 ± 8.5 years. Overall, 64 IBE devices were implanted in The Netherlands during the study period. Forty-five patients

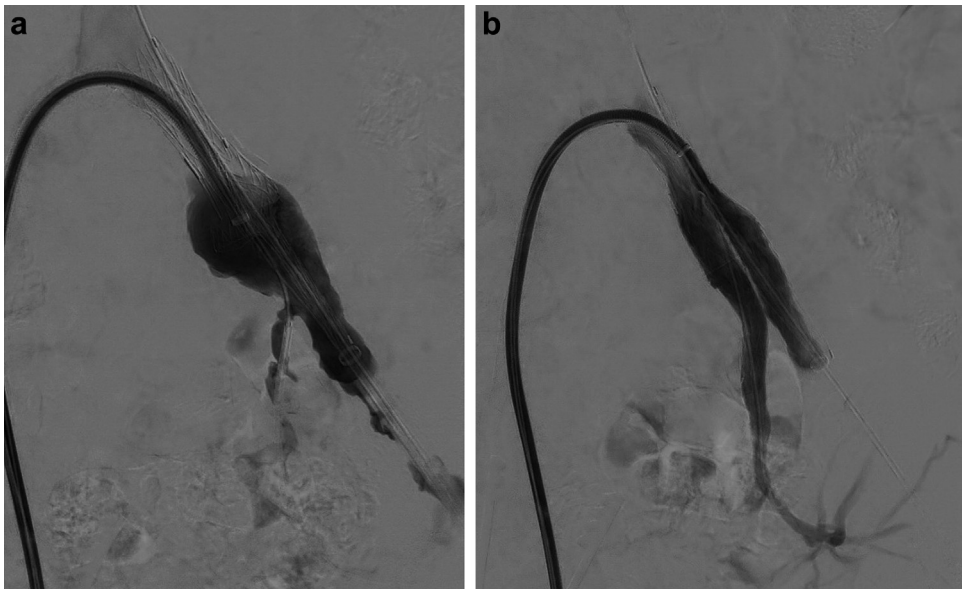

Fig 3. a and **b,** Procedural fluoroscopy to illustrate the deployed iliac branch endoprosthesis (IBE) device with the cross-over sheath in the body of the device.

(97.8%) were male. All patients were treated in an elective setting but two (4.3%) were considered symptomatic.

Anatomical characteristics are depicted in Table I. The treated CIA aneurysm was located at the right side in 27 cases (58.7%), and five patients were treated with a bilateral IBE (10.9%). The median (range) diameter of the treated CIA aneurysm was 40.5 (25.0-90.0) mm. In 15 cases (32.6%), the infrarenal aorta had a diameter of ≥55 mm, and 19 others (41%) had an aortic diameter of ≥30 to 55 mm. In one patient, the distal landing zone in the IIA was less than the required 10 mm in length. The distal landing zone in the EIA was always >10 mm in length. In seven patients (15.6%), the anatomy of the aneurysm was outside the IFU for the IBE device.

Preoperatively, five patients suffered from intermittent claudication. One patient had claudication of the buttock and four patients had claudication of the thigh or calf, or a combination of both. The preoperative symptoms were ipsilateral of the IBE-treated side in 2 patients, contralateral in 1 patient, and unknown in 2 patients. One patient complained of erectile dysfunction, but information on erectile function was missing in 23 cases. Antihypertensive drugs were used by 60.9% (n = 28), platelet inhibitors by 69.6% (n = 32), coumarin derivates by 23.9% (n = 11), and statins by 70.1% (n = 35) of cases. The American Society of Anesthesiologists classification was 1, 2, 3, and 4 in, respectively, 1, 24, 15, and 1 case and was missing in the remaining five cases.

Procedure. Most patients (n = 44; 95.6%) received surgery under general anesthesia and the other two under local and regional anesthesia, respectively. Access was acquired by surgical cutdown in 43 patients (93.5%) and percutaneous in the remaining patients. The contralateral IIA was patent and preserved in 29 patients (63.0%), embolized before the procedure in 2 patients (4.3%), embolized and overstented during the procedure in 7 patients (15.2%), and not patent before the procedure and overstented during the procedure in 3 patients (6.5%). The decision-making process on the management of the contralateral IIA was dependent on local protocols and the individual surgeon. In one patient, it was not possible to implant the IBE. In that case, the internal component dislocated during placement and an attempt to implant a second one failed. Embolization and overstenting was performed instead. In the remaining five patients, both IIA

Table I. Anatomical characteristic of the cohort of 46 patients with a CIA aneurysm treated with the GORE EXCLUDER iliac branch endoprosthesis (IBE) device

Characteristic	*Size (range), mm*
Maximum diameter right CIA	39 (12-90)
Maximum diameter left CIA	31 (12-73)
Length right CIA	70 (44-182)
Length left CIA	68 (40-155)
Maximum diameter right IIA	10 (3-18)
Maximum diameter left IIA	10 (6-21)
Maximum diameter right EIA	12 (9-17)
Maximum diameter left EIA	12 (7-15)
Diameter infrarenal aortic neck	22 (18-30)
Maximum diameter infrarenal aorta	45 (19-80)

CIA, Common iliac artery; *EIA,* external iliac artery; *IIA,* internal iliac artery.
Data are presented as median and range.

were treated with an IBE device. In six patients, the IBE was placed for a CIA aneurysm without the addition of a GORE EXCLUDER bifurcated aortic endograft. No conversions to open repair were needed.

There were six residual endoleaks in five patients at the end of the procedure, of which 3 type II, 2 type Ib, and 1 case in which the endoleak could not be defined. The two type Ib endoleaks, derived from the IBE component, were considered minor and left untreated. The diameters of the IIA were 10 and 11 mm, respectively, and treated with a 14-mm iliac component. The landing zones were >10 mm in both cases, with circular calcium in one of them. These two procedural type Ib endoleaks and one implant failure rendered the procedural success rate to be 93.5%. The overall mean surgery time was 198.3 ± 56.2 minutes, with a mean fluoroscopy time of 41.5 ± 14.4 minutes. The median (range) time of hospitalization was 3.0 (2.0-8.0) days. At discharge, 28.3% of the patients (n = 13) were prescribed coumarin derivates, 78.3% (n = 36) platelet inhibitors, 84.8% (n = 39) statins, and 67.4% (n = 31) antihypertensive drugs. Three patients had adverse events: 1 had atrial fibrillation and delirium, 1 had seroma of both groins, and 1 had decubitus.

Thirty-day outcome. At 30-day follow-up, no reinterventions were performed. There was one occlusion of the treated IIA, which was observed on a CT angiography scan during admission of a patient who was treated inside the IFU. Because this patient did not have any complaints, no reintervention was performed. In this patient with a diameter of the right CIA of 35 mm and an IIA of 9 mm with a length of 22 mm, the IBE branch was intentionally delivered in a secondary branch of the IIA of 6 mm. Calcification and tortuosity was mild. There were five wound-related complications, including superficial wound infection (n = 2), wound dehiscence (n = 1), and seroma (n = 2). The two type Ib endoleaks seen during the surgery resolved spontaneously. Three patients had buttock claudication: one patient who was treated with a bilateral IBE had new-onset buttock and thigh claudication at both sides without loss of patency of the IBE and confirmed with CT angiography. The other two patients had buttock claudication at the contralateral side. In one patient, this can be explained because the contralateral IIA was embolized and overstented, but in the other patient, the IIA was patent. One patient mentioned onset of erectile dysfunction (2.5%), although information on erectile dysfunction was not always available. Colonic or spinal cord ischemia was not observed. Other outcome data are listed in Table II.

Last follow-up. Short-term follow-up was available for 28 patients who had 32 IBE devices implanted. One patient died 4 months after the procedure due to congestive heart failure. The mean follow-up of all patients who had follow-up after 30 days was 5.6 months (range, 1.8-12.2 months). Two reinterventions were performed: one patient required the placement of a balloon-expandable stent for an asymptomatic external iliac limb stenosis, and another patient had an Amplatzer (St. Jude Medical, St. Paul, Minn) plug placed in the IIA limb for a new type Ib endoleak. Initially, this patient was treated according to the IFU for the device. The primary patency of the IIA limb device at 6 months was 93.8%. After a mean follow-up of 6 months, data on 17 treated aneurysms were available. Two showed a stable diameter, whereas 15 showed a mean decrease of 3.9 ± 2.2 mm ($P < .001$). Information on claudication was complete in 21 of 28 patients and on erectile dysfunction in 18 of 26 male patients. One new patient suffered from buttock claudication due to an occlusion of the left IIA at the side treated with the IBE device. This patient was successfully treated with supervised walking exercise. One new patient reported new erectile dysfunction without loss of patency.

Table II. Follow-up data of the cohort at 30 days and 6 months

Follow-up	*At 30 days (n = 40)*	*At 6 months (n = 28)*
Mortality	0 (0)	1 (4)
Reinterventions	0 (0)	2 (7)
External iliac limb stenosis/occlusion	1 (3)	1 (4)
Internal iliac limb stenosis/occlusion	1 (3)	2 (7)
Endoleak	6 (15)	5 (18)
Type Ib	0 (0)	1 (4)
Type II	5 (13)	4 (14)
Unknown	1 (3)	0 (0)
Intermittent buttock claudication		
Contralateral	2 (5)	0 (0)
Ipsilateral	2 (5)	1 (4)
Erectile dysfunction	1 (3)	2 (7)

Data are presented as number (%).

DISCUSSION

In the present study, we have shown that implantation of the GORE EXCLUDER IBE device leads to high procedural success, low reintervention rates, and high short-term patency. At the 6-month follow-up, IIA patency was lost in two cases and reinterventions were performed in two of 46 patients. Iliac branched devices appear to be a step forward in the era of endovascular treatment of aortoiliac aneurysmal disease with preservation of flow to the ipsilateral IIA. Although the incidence of ischemic complications due to overstenting or coiling are considered low, percentages of up to 22% have been described.[14] Thus, there seems to be a possible improvement of results by preservation of iliac flow, especially in young active patients. These ischemic complications, but also potential future thoracic interventions in case of progression of disease, justify the preservation of IIAs.[15] In the present series, the contralateral IIA was overstented in six cases, and it was preserved with a bilateral IBE in five others. Which strategy should be preferred, considering clinical consequences and costs, cannot be concluded from this case series.

Besides the relatively high costs, limitations in the branched techniques are mainly found in the anatomical requirements. Evidence so far is limited to case series using the Cook IBD device. Parlani et al[12] described the results of 100 consecutive patients who were enrolled in a prospective database. The procedural success rate was 95%. At a median follow-up of 21 months, two distal type I endoleaks occurred. The estimated patency of the internal iliac branch was 91% at 1 year. Earlier, Karthikesalingsam et al[11] published a systematic analysis of nine studies including seven series and 196 patients. Technical success varied between 85% and 100%. Occlusion of the treated IIA occurred immediately after surgery in 6 patients (3.1%), at <30 days in 11 patients (5.6%), and during follow-up in 7 patients (3.6%). In these 24 patients, 50% experienced buttock claudication. The reintervention rate was rather low with only 12 patients (6%), although follow-up is still very limited. Ferrer et al[16] reported in 2014 their initial experience with the IBE device in five patients. Technical success and iliac branch patency was 100%. One reintervention was necessary concerning a narrow aortic bifurcation. Ferrer et al[16] considered the dedicated IIA stent on the basis of the GORE EXCLUDER design and the high conformability of the external iliac segment as a step forward in iliac branched grafting. The flexibility of the main body of the device and the option for repositioning are new in relation to other prostheses. These features could lead to better results in tortuous iliac systems and short CIAs. In patients with extensive aneurysmal disease, the preservation of the iliac collateral bed is essential to prevent spinal cord ischemia when additional thoracic aneurysm repair is required.[14]

Results from the present analysis are well in line with the aforementioned data published on the Cook IBD device. Although the IFU for IBE is conservative, seven of the 46 (15.6%) patients were treated outside of the IFU. The patency of the IIA branch at 6 months was 94% and the occlusions that occurred did not have evident clinical effect. One of the IIA branches was intentionally occluded to treat a type I endoleak. Ipsilateral buttock claudication was present in only two cases at 30 days and disappeared during follow-up. The incidence of reported erectile dysfunction was low and severe ischemic complications were absent.

The present study has limitations. Because of the retrospective design, data were not always complete and especially clinical data like erectile dysfunction were often missing and not reported in a standard fashion. Moreover, the management of the contralateral IIA was not standardized and this can markedly affect clinical outcome. The mean follow-up time was short. Thirteen hospitals have participated in this study, introducing biases like learning curve and differences in case selection. Moreover, follow-up data were not available for every patient. These limitations have emphasized the need for a prospective multicenter registry on the IBE device that is currently ongoing (Iliac Branch Excluder ReGistry [IceBERG]; ClinicalTrials.gov NCT02345005). Hopefully, this trial will give us more answers on indication and outcomes.

On the basis of the current literature, we cannot advise on which anatomies are suitable or less suitable for iliac branched devices, and also the sample size of the current study is too small to study subsets of anatomical variations. However, we believe that especially in the young active patient, both IIAs and in the high-risk patient with extensive aneurysmal disease, at least one IIA should be preserved; preserving techniques and coiling are indicated to establish the position of this specific device. In addition, comparative trials with competitor devices but also older iliac-preserving techniques and coiling are indicated to establish the position of this specific device.

CONCLUSIONS

The use of the GORE EXCLUDER IBE device for CIA aneurysms results in high procedural success and IIA, patency rates. Prospective data are awaited to establish the role of the device in the treatment algorithm of CIA aneurysms.

The help of Elke Mathijssen and Suzanne Holewijn with the statistical analysis of the data is greatly appreciated, as is the collaboration of involved investigators in the 13 sites.

AUTHOR CONTRIBUTIONS

Conception and design: SS, MB, MR
Analysis and interpretation: SS, MB, MR
Data collection: MB
Writing the article: SS, MR
Critical revision of the article: SS, JH, MB, HV, DE, MS, CZ, MR
Final approval of the article: SS, JH, MB, HV, DE, MS, CZ, MR
Statistical analysis: SS, MB, MR
Obtained funding: Not applicable
Overall responsibility: SS

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Supplementary Table. Investigational sites and investigators

Investigative site	*Location*	*Investigators*
Albert Schweitzer Hospital	Dordrecht	J. Avontuur
Bernhoven Hospital	Uden	T. Smits
Catharina Hospital	Eindhoven	M.R. van Sambeek
Deventer Hospital	Deventer	R.B.M. van Tongeren
Erasmus Medical Center	Rotterdam	H.J. Verhagen
Maasstad Hospital	Rotterdam	G. Akkersdijk
Medical Center Haaglanden	The Hague	D. Eefting
Nij Smellinghe	Drachten	O.R.M. Wikkeling
Orbis Medical Center	Sittard	C.J.J.M. Sikkink
Rijnstate Hospital	Arnhem	M. van Bladel S. Holewijn E. Mathijssen M.M.P.J. Reijnen S.M.M. van Sterkenburg
St. Elisabeth Hospital	Tilburg	J.M.M. Heyligers T. Koëter
St. Fransiscus Hospital	Rotterdam	J. van Brussel
University Medical Center Groningen	Groningen	C.J. Zeebregts I.F.J. Tielliu